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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/534,423
Filing Date: May 10, 2005
Appellant(s): HAYASHI ET AL.

Walter C. Pledger
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 19, 2010 appealing from the Office action mailed July 16, 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 39-76 are pending and have been finally rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

WO00/51815	Roreger et al. (using US Patent 6,818,087 as translation)	9-2000
WO02/087622	Nogami (Using US PreGrant Publication 2004/0137040 as translation)	11-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Appellant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 39-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al. (WO document 00/51815 (German) using US Patent 6,818,087 as translation (note that due to a typographical error, this was previously cited as 02/51815; however the 6,818,087 patent clearly identifies it as 00/51815)) in view of Nogami (WO document 02/87622 (Japanese) using US PreGrant Publication 2004/0137040 as translation).

Appellant claims

Appellant claims a method and apparatus for manufacturing a multilayer edible film composition for administering an active agent.

Determination of the scope and content of the prior art (MPEP 2141.01)

Roreger et al. teach, as a whole, a method and apparatus for manufacturing a layered film composition containing an active agent.

Claims 39, 49, 56, & 62: Roreger et al. teach uniting two base material (or agent-containing) layers (**1** & **2** in Fig.1) together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (**13** in Fig.1). Roreger et al. teach the base layers provided on both sides with protective layers (**3** & **4** in Fig.1) and peeling (delaminating) a protective layer, such as paper, plastic (resin films) or textiles, off of the base material layers (column 4, lines 37-49). Determination of the arrangement of the delaminating apparatus (substantially tangential) and of selection of which protective layers (resin films) to be removed is within the purview of the skilled artisan. Repeating the steps of laminating another base material layer on and delaminating its protective cover would also be within the purview of a skilled artisan. Roreger et al. teach the base materials being provided on stock rolls (column 4, lines 37-49), which means the step of winding the layers onto a roll would be necessarily carried out. Determining the size of the delamination roll (winder) would have been routine in the art and is not crucial to the invention in the absence of evidence to the contrary.

Claims 40, 50, 51, 57, 58, & 63: Roreger et al. teach that the protective layers are treated with silicone to be rendered detachable (column 4, lines 37-49). Determining

which sides of which compositions would receive this treatment is within the purview of the skilled artisan.

Claims 41, 52, 58, & 65: Roreger et al. teach the pressure of the laminating step is 2 to 10 bars (0.2 to 1 MPa) which is inside the claimed range (column 5, lines 62-65).

Claims 42, 44, 45, 53, 59, & 66: Roreger et al. teach thermally conditioning the laminating equipment (column 5, lines 60-61) to achieve a desired viscosity in the base material. Though Roreger et al. do not teach a temperature at which the laminating is accomplished, it would be within the purview of the skilled artisan to determine the optimum temperature to insure binding by routine experimentation.

Claim 43: Roreger et al. teach that after binding the layered composition is cooled to a temperature of 3 to 10°C (column 6, lines 55-57).

Claims 46, 54, 60, & 67: Roreger et al. teach a base material that is 36 and 80 μm thick (example, column 7, lines 1-16).

Claims 47, 55, 61, & 68: Roreger et al. teach that the base materials are self-supporting laminate films (example, column 7, lines 1-16).

Claim 48: Roreger et al. teach removing the protective layers (column 4, lines 37-49). Determining when to remove the protective layer and which layers to remove is within the purview of the skilled artisan.

Claims 69-71: Roreger et al. teach uniting two base material (or agent-containing) layers (**1** & **2** in Fig.1) together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (**13** in Fig.1). Roreger et al. teach the base layers provided on both sides with protective layers (**3** & **4** in Fig.1) and peeling

(delaminating) a protective layer, such as paper, plastic (resin films) or textiles, off of the base material layers (column 4, lines 37-49) and onto winding rolls (**5** & **6** in Fig.1). Determining the size of the delamination roll (winder) is would have been routine in the art and is not crucial to the invention in the absence of evidence to the contrary.

Claim 72: Roreger et al. teach the unwinding rolls (**1a** and **2a** in Fig.1) and the winding rolls (**5** & **6** in Fig.1), and it would be within the purview of the skilled artisan to determine the size of the rolls through routine experimentation.

Claim 73-76: Roreger et al. teach that the composition can be cut after bonding (column 6, lines 58-60). The claims further describe a system for receiving the finished product and storing on a plurality of wheels. Roreger et al. teach a single wheel to receive the product (see Fig.1, unlabeled element below **14**) and the duplication of this element for each of the cut-down film compositions would have been obvious to the skilled artisan.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between Roreger et al. and the instant claims is that Roreger et al. do not expressly teach edible films and the methods of making the drug-containing films. This deficiency in Roreger et al. is cured by the teachings of Nogami.

Nogami teaches, as a whole, a layered edible film composition for administering an active agent.

Claims 39-76: Nogami teaches making the layers by applying (spray coating) a solution onto a (resin) film and drying it (manufacturing example 1, paragraph 109).

Nogami teaches the drug-containing layer is made of an edible polymer including cellulose and cellulose derivatives preferably hydroxypropylcellulose and hydroxypropyl-methylcellulose phthalate (paragraph 54). Nogami teaches that the multilayered composition can be made by thermally fusing two medicinal agents together through and intermediate adhesive layer (paragraph 103 and figure 11). Nogami et al. teach that many of the same polymers can function as both the base for drug-containing layer and adhesive intermediate layer (paragraph 51 and 84), therefore the layers could be integrated to form a single layer adhesive/drug-containing layer, especially since Nogami teaches the possibility of two drug layers being adjacent (paragraphs 49 & 81). Though Nogami teaches a composition having a water-swellable layer between the film and the drug-containing layer (paragraph 109), this layer is not excluded by the instant claims' use of the term comprising.

As to the claimed non-permeation of one layer into another, where the claimed and prior art products are substantially identical in structure or composition, or are produced by substantially identical processes, a *prima facie* case of obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent appellant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and appellant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to appellant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the

claimed non-permeation of one layer into another, since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the edible, layered, active agent-containing composition of Nogami by using the films in Nogami as the base layers in the laminate composition-producing method and apparatus as taught by Roreger et al. and produce the instant invention. The skilled artisan would have been motivated to make the layered film compositions in this manner because Nogami suggests forming multilayer film compositions by making two halves of the composition and thermally fusing them under pressure (paragraph 108).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in making the edible layered active agent composition of Nogami by a modified laminate composition-producing method and apparatus as taught by Roreger et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

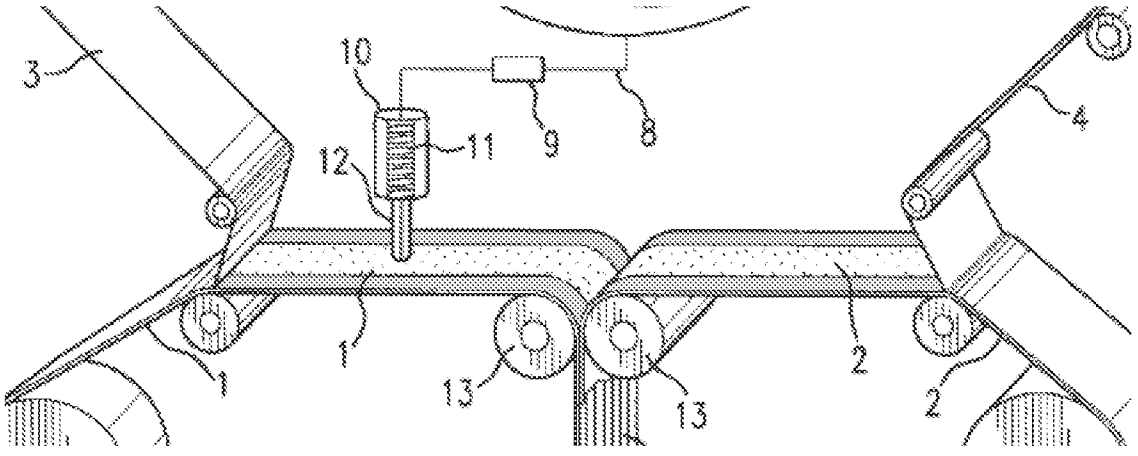
(10) Response to Argument

The examiner has fully considered appellant's arguments.

In its most basic and simple terms, the rejection is based on making the film compositions of Nogami (i.e. using the individual agent-containing layers of Nogami and the suggestion of heat fusing said layers) through the use of a modified (in the sense of parts being duplicated or rearranged in an obvious manner) version of the apparatus of Roreger. Nogami teaches making edible-agent containing layers by coating and drying resin films (*supra*). These edible agent-containing layers with their (resin) film backings are then used as the starting materials in Roreger (i.e. as **1a** & **2a** in Fig.1). Roreger teaches pressing them together to bond them (an action also at least suggested by Nogami). In other words, the edible agent-containing films of Nogami are used as the base material layers in Roreger (i.e. **1** & **2** in Fig.1). Since Roreger teaches steps of delaminating the protective layers, it would have been obvious to remove a remaining protective layer after the pressure-bonding of the films.

Appellant's argument based on the assertion that **1** & **2** correspond to the resin films of the claims (1st two full paragraphs on page 10 of the appeal brief) lacks an understanding of the rejection as it applied. As laid out above, the rejection is based on substituting the active-agent films of Nogami in as elements **1** & **2** of Roreger. In order to adopt appellant's interpretation one is required to completely ignore the teachings of Nogami (*supra*), and further ignore the teachings of Roreger as to the protective layer **3** & **4** (*infra*).

Appellant's arguments (following the assumption that **1** & **2** are the edible agent layers) are largely based on the belief that neither Roreger nor Nogami teach nor suggest delaminating one of the two resin films that "sandwich" the bonded edible agent layers. This assertion is premised on appellant's assertion that "Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance, and therefore the protective layers 3 and 4 never sandwich the active substance" (page 10 of Appeal Brief, emphasis original). This premise is factually incorrect. Roreger specifically teaches that "both layers (**1**, **2**) are provided on *both sides* with protective layers (**3**, **4**)" (Roreger, column 4, lines 39-41, emphasis added). Therefore when one of these protective layers is removed in the course of the method taught by Roreger, the other remains with the bas material layer. The protective layers left behind, though not specifically identified by Roreger in Fig.1, are clearly shown (shaded in solid gray by the examiner) in the portion of Fig.1 shown below.



Since these protective films clearly remain with the base materials through the step of pressure-bonding, appellant's assertion that "layers 3 and 4 never sandwich the active substance" is clearly incorrect.

Appellant's arguments concerning Roreger's teaching of the irreversible bonding is also based on this incorrect premise. Appellant argues that, contrary to the examiner's assertion that one of ordinary skill in the art would then be able to use a winding roll as taught by Roreger to remove a protective film after pressure bonding, the irreversible bonding of layers **1** & **2** taught by Roreger would prevent that. However, this argument is based again on appellant's now rebutted premise that "layers 3 and 4 never sandwich the active substance". In other words, appellant did not believe that there was a protective (resin) film to remove following the pressure-bonding step, whereas clearly the examiner has demonstrated that there is. As such, appellant's argument about the removal of only one protective (resin) film is not convincing as appellant seemingly ignores the examiner's argument that Nogami teaches this element only to instead argue that a film removal step cannot be used with Roreger as there are no more protective films to remove. The examiner has demonstrated that this interpretation of Roreger is incorrect, and as such it would have been obvious to remove none, one, or both protective films depending on the desired further processing (storage, cutting, direct patient administration, etc.). Similalry, appellant's argument that the modification of placing a winding a reel after the pressure-bonding component of the apparatus rendering Roreger unsuitable for its intended use is also defectively premised on the belief that the protective films are not present following pressure-bonding.

Finally appellant argues that neither reference teaches adding a third layer to the film formulation. The examiner has previously argued that "Repeating the steps of laminating another base material layer on and delaminating its protective cover would

also be within the purview of a skilled artisan". Specifically, no special skill is necessary to meet this limitation as all it requires is taking the finished 2-layer film product wound onto a roll and replacing one of the single layer film starting materials (**1a** or **2a**) with the wound two-layer composition.

In summary, the examiner has clearly demonstrated that appellant has misconstrued the express teachings of the Roreger reference. All of appellant's arguments are based on this faulty premise. Every element of the claims is either expressly taught or suggested by the references, and all elements are performing their art-recognized functions; therefore, the expectation of success is reasonable. Therefore the subject matter of the claims is obvious within the meaning of 35 U.S.C. § 103(a).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/C. R. L./

Examiner, Art Unit 1619

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